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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,899	08/31/2001	Arnold Miller	AM-4A	3897

7590

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EXAMINER

BAXTER, JESSICA R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,899

Applicant(s)

MILLER, ARNOLD

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-11,13,15,19-22,26-29 and 31-34 is/are rejected.
- 7) ☒ Claim(s) 2,5,12,14,16-18,23-25 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-31 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3,4, 6-11, 13, 15, 19-22, 26-29, 31 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/16701 to Parodi et al. in view of U.S. Patent No. 5,957,940 to Tanner et al.

Parodi discloses a method for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said method comprising: providing apparatus for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway (assembly 60), said apparatus comprising: a delivery tube having third and fourth ends, first and second tube portions adjacent to said third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends (tube 72), said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition (FIGS. 12 and 14), said third stressed elongate shape enabling said third end to be extended through an endovascular pathway,

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with said fourth unstressed shape being formed with said first and second tube portions being configured at an angle to one another (FIG. 14); delivery tube deployment tube directly engaging said delivery tube being configurable between a first position and a second position (control 68), said first position of said delivery tube deployment tube restraining said delivery tube in said third stressed elongate shape, and said second position of said delivery tube deployment tube releasing said delivery tube in said fourth unstressed shape (FIGs 12 and 14); penetration means adjacent said third end of said delivery tube (end 82), said penetration means being configured to pierce through a vascular structure in the endovascular pathway (FIG. 16); and insertion means (handle 144) adjacent to said third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means; placing said delivery tube adjacent said vascular structure, with said delivery tube being configured in said third stressed elongate shape (FIG. 12); deploying said delivery tube from said third elongate shape to said forth elongate shape with said delivery tube deployment means (FIG. 14), said deployment of said delivery tube placing said third end adjacent to the vascular structure in the endovascular pathway; penetrating the vascular structure in the endovascular pathway with said penetration means (FIG. 16), said penetration of the vascular structure being performed at said third end of said delivery tube; and inserting said surgical fastener through the plurality of portions of material using said insertion means, said insertion of said surgical fastener being performed from inside of said vascular structure (FIGs 12, 14 and 16). Parodi does not disclose providing a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, said first stressed elongate shape of said fastener enabling said first end to be extended through a plurality of layers of material, and with said second shape of the element being in the form

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of a spring with a plurality of coils around a spring axis, with said coils being spring biased towards each other along said spring axis with sufficient axial force so as to enable coils on opposite sides of layers to clamp the layers of material together along spring axis. Tanner teaches that a particular self-expanding fastener may be used to secure a prosthesis to a vessel wall under a compressive force (Column 6 lines 21-26) in place of a non self-expanding fastener (Column 21 line 30-Column 23 line 24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the fastener of Parodi with the fastener of Tanner since Tanner teaches that both a fastener similar to that of Parodi (Tanner FIGS 29 and 30) may be replaced with a fastener that has a plurality of coils and a spring axis (Tanner FIG 32) since these types of fasteners are interchangeable as taught by Tanner.

Regarding claim 4, Parodi does not disclose the super elastic material is Nitinol. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device out of Nitinol, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claims 8 and 27, Parodi discloses that said insertion means is a plunger being configured within said delivery tube (handle 144), said plunger having first and second portions, said first and second portions being configured adjacent said third and fourth ends of said delivery tube, respectively, said first end of said plunger being configured adjacent said second end of said fastener, whereby movement of said plunger a predetermined distance toward the third end of said delivery tube forces said fastener through said vascular structure a distance corresponding to said predetermined distance (FIG. 12, 14 and 16).

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Regarding claim 9 and 22, Parodi discloses a guide wire (wires 77) having a given stiffness for allowing positioning within the endovascular pathway of said vascular structure, said guide wire having a longitudinal axis, said first stressed elongate shape of delivery tube being configured in parallel to said guide wire.

Regarding claims 10 and 11, Parodi discloses a balloon catheter supported by said guide wire (66).

Regarding claim 13 and 15, Parodi discloses an endovascular graft (graft 100) being in surrounding configuration to said third end of said delivery tube wherein said surgical fastener delivered by said delivery tube attaches said endovascular graft to the vascular structure in the endovascular pathway.

Allowable Subject Matter

4. Claims 2, 5, 12, 14, 16-18, 23, 24, 25 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments with respect to claims 1-31 are have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
jrb

August 25, 2003

Julian W. Woo
Julian W. Woo
Primary Examiner